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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,267	08/10/2001	Christopher D. Creech	018512-006510US	6230

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EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	18

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,267	CREECH ETAL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed in Paper No. 17 on July 11, 2003 has been entered in full. Claims 5, 6, 9-18, and 21-40 are canceled. Claims 7, 8, and 19 have been amended. Claims 1-4, 7, 8, 19, and 20 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Withdrawn Rejections

Applicants' cancellation of claims 5, 6, and 9 has made the rejection of claims set forth in Paper No. 16 moot.

The rejection of claim 8 under 35 U.S.C. § 112, 1st paragraph (Written Description), as set forth in paper No. 16, has been with drawn in view of Applicants' amendment to the claim.

The rejection of claims 7 and 8 under 35 U.S.C. 112, second paragraph, as set forth at pages 8 and 9 in Paper No. 16, has been withdrawn in view of Applicants' argument.

III. Claim Rejections Under 35 U.S.C. § 101

The rejection of claims 1-4, 7, 8, 19, and 20 under 35 U.S.C. §101, as set forth at pages 3-4 of the previous Office Action (Paper No. 16, April 8, 2003), remains.

At the bottom of page 4, Applicants cites MPEP and case law on the standard to assess utility. There is no dispute on the utility requirement under 35 U.S.C. §101 and the case law. The issue at dispute is what constitutes a specific and substantial utility.

At the middle of page 5, Applicants argue that the human CNG2B gene is orthologous to the rat OCNC2 gene and therefore polypeptides encoded by the two genes share the same physiological functions.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the specification asserts that "the human CNG2B gene appears to be orthologous to the rat OCNC2 gene, suggesting that it serves a similar functional role" (bottom of page 62 of the specification). This assertion clearly indicates that significant further research is required to determine the specific biological functions of the polypeptide encoded by the human CNG2B nucleic acid. Secondly, the specification asserts that the human CNG2B gene shows homology with rat OCNC2 and that the amino acid sequence of human CNG2B is 93% identical to that of rat OCN2. However, the only supporting evidence is that both human CNG2B and rat OCNC2 gene are expressed in brain tissues. The specification fails to provide any experimental data or sufficient information on whether the CNG2B protein functions like a cyclic nucleotide-gated channel. It is noted that while the amino acid sequence encoded by human CNG2B shares 93% homology with that of rat OCNC2, they are still not the same molecules.

At the beginning of page 6, Applicants argue that the present invention has a specific utility. Applicants submit that Applicants disclose a "disease condition", i.e.,

altered olfactory signal transduction, that correlates with a "biological activity", i.e., the opening and closing of CNG cation channels.

Applicants' argument has been fully considered, but is not deemed to be persuasive because a specific utility has to be specific to the claimed subject matter. In the instant case, the specification has not disclosed a specific disease that is associated with the claimed molecules or can be treated. A "disease condition", i.e., altered olfactory signal transduction, is too ambiguous and fails to identify a specific disease. Likewise, a "biological activity", i.e., the opening and closing of CNG cation channels fails to define a true biological function or any physiological significance. In addition, the term "CNG cation channel" fails to indicate specifically which cation ions are controlled by the channel; does the channel control all cation ions or it only controls the influx of Na^+ and Ca^{2+}? Thus, the asserted utility is not specific.

At the middle of page 6, Applicants argue that the present invention has a substantial utility or a "real-world' use. Applicant submit that the present invention provides CNG cation channels, discloses that CNG cation channels modulate signal transduction in olfactory, and teaches how to identify modulators of the cation channels. Therefore, there is a real-world use of the invention in the modulation of olfactory sensation, as well as in the identification of compounds that modulate CNG2B channels and thus can be useful as therapeutic agents for treating diseases related to altered olfactory signal transduction.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the specification fails to define a specific biological function or any physiological significance of the claimed molecules and fails to specify a specific

disease associated with the molecules of the present invention for the reasons set forth immediately above. Thus, significant further research is needed to determine the specific biological functions of the molecules of the present invention and to determine any diseases that are involved in the molecules of the present invention.

Beginning at the bottom of page 6, Applicants submit that the Examiner has not established a prima facie showing of lack of utility. Citing MPEP, Applicants submit that the initial burden is on the Examiner, not Applicants, to provide evidence to support a factual conclusion of the credibility of an asserted utility. The Examiner notes that since the asserted utility is not specific and substantial, the credibility of the asserted utility has not been assessed. It is further noted that the instant application was filed on 10 August 2001. No evidence on the specific biological functions or any physiological significance of the present molecules has been brought forth in an appropriate form during the prosecution history. It is clearly in favor of Examiner's position that significant further research or undue experimentation is required to identify such information. Thus, a prima facie showing of lack of utility has been established.

IV. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph (Enablement)

The rejection of claims 1-4, 7, 8, 19 and 20 under 35 U.S.C. § 112, 1st paragraph remains. The basis for this rejection is set forth at pages 5-6 of the previous Office Action (Paper No. 16, April 8, 2003).

Applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reason set forth above.

The scope enablement rejection of claims 1, 3, 7, 19, and 20 set forth in the previous Office Action (Paper No. 16, April 8, 2003) also remains.

Applicants argue that the application teaches that a known CNG polynucleotide sequences (such as SEQ ID NO: 2 and 3) may be used as a hybridization probe for screening and identifying other CNG2B nucleic acids.

Applicants' argument has been fully considered, but is not deemed to be persuasive because a method of finding a molecule, as in the instant case, is not equivalent to a method of making a molecule. The specification fails to provide any sufficient guidance and any working examples regarding how to make and use the homologues, variants, alleles, and mutants of the CNG2B nucleic acid. The specification fails to define the biological functions or any physiological significance of the molecules of the present invention. Furthermore, the specification is silent with respect to the conserved regions that are critical to the structure and function of the genus claimed or the sites at which variability may be tolerated without loss of activity. Without defined structural and functional limitations, it would require undue experimentation for one skilled in the art to make and use the homologues, variants, alleles, and mutants of the CNG2B nucleic acid.

Applicants argue that the functional feature of CNG2B polypeptides does define the claim scope. Applicants submit that a functional feature (e.g., characteristic of cyclic nucleotide-gated cation channel) commonly shared by the claimed nucleic acids is readily testable according to the methods disclosed in the present invention as well as other methods known to those skilled in the art.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the specification fails to define a specific biological function or any physiological significance of the molecules of the present

invention, as noted above. The activities of a cation channel disclosed in the specification (page 42) to be used in assays, e.g., measuring current, membrane potential, ion flux, ion concentration, second messengers and transcription levels, or ligand binding are not specific to the claimed cyclic nucleotide gated cation channel. Secondly, claims 1 and 3 recite an isolated nucleic acid encoding a polypeptide comprising a subunit of a cation channel, the polypeptide forming a cation channel having the characteristic of cyclic nucleotide-gating, whereas claim 7 recites an isolated nucleic acid encoding a cyclic nucleotide gated cation channel 2B polypeptide. Since the "activity' recited in the claims are ambiguous and not specific to the cyclic nucleotide gated cation channel of the present invention, they do not effectively limit the scope of claims.

V. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph (Written Description)

The rejection of claims 1, 3, 7, 19, and 20 under 35 U.S.C. § 112, 1st paragraph, as set forth at pages 6-8 of Paper No. 16, remains.

Beginning at page 10, Applicants argue that the pending claims meet the Lilly standards. Specifically, applicants submit that claims 1 and 8 set forth both structural and functional elements and thus the claimed nucleic acids are defined via shared functional and structural properties.

Applicants' argument has been fully considered but is not deemed to be persuasive for the following reasons. First, the asserted functional elements, e.g., encoding a cyclic nucleotide gated cation channel CNG2B or a subunit of a cation channel do not represent a clearly defined function of the molecules of the present invention, as noted above, and thus fail to limit the scope of the claims. Secondly, the

sequence percentage identity does not represent an effective structural limitation (unless it is 100% identical) because it says nothing about the conserved regions that are critical to the structure and function of the genus claimed or the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Furthermore, there is no disclosure of examples of homologues, variants, alleles, and mutants of the CNG2B nucleic acid. Thus, while the specification provides an adequate written description for the nucleic acids of SEQ ID NOS: 2 and 3 or an nucleic acid encoding the amino acid sequence of SEQ ID NO: 1, it fails to provide adequate or sufficient written description for its homologues, variants, alleles, and mutants.

Beginning at the middle of page 11, Applicants argue that description of species can properly support the description of a genus. Specifically Applicants submit that two representative species (SEQ ID NOS: 2 and 3) have been provided as examples of the claimed genus of CNG nucleic acids.

Applicants' argument has been fully considered but is not deemed to be persuasive because the two nucleic acids set forth in SEQ ID NOS: 2 and 3 encode the amino acid sequence of SEQ ID NO: 2, do not encode homologues, variants, alleles, or mutants of SEQ ID NO: 2, and thus are not representative species of the genus.

At the middle of age 12, Applicants argue that the asserted functional feature does describe the claimed genus. Applicants submit that the examiner has not provided specific evidence and scientific reasoning why the asserted functionality is not credible.

Applicants' argument has been fully considered but is not deemed to be persuasive because the specification fails to define a specific biological function or any

other physiological significance, as noted above and recitation of an ambiguous "activity" does not provide a functional description for the claimed invention.

At top of page 13, Applicants submit that Fiddes v. Baird is not inconsistent with the standards for written description as set forth by Lilly or Fiers. The Lilly decision would be controlling over Fiddes, if any inconsistency existed. The Examiner does not dispute.

Beginning at the middle of page 13, Applicants argue that the fact pattern of Fiddes is not analogous to that of the present case. Applicants submit that the Board in Fiddes did not take the position that the claim of a genus cannot be adequately supported by the disclosure of an accurate polynucleotide sequence. Nor could the Board, under Lilly, properly require the claim of a genus to be supported by Applicant's possession of every embodiment of the genus.

Applicants' argument has been fully considered but is not deemed to be persuasive for the following reasons. While the specific situations in the instant case and in Fiddes's case vary, they do share one thing in common, that is, lack of description for the claimed invention. As noted above, while the specification provides an adequate written description for the nucleic acids of SEQ ID NOS: 2 and 3 or an nucleic acid encoding the amino acid sequence of SEQ ID NO: 1, it fails to provide adequate or sufficient written description for its homologues, variants, alleles, and mutants because two representative species (SEQ ID NOS: 2 and 3) are not representative species of the genus. In addition, the asserted structural and functional features do not effectively describe the claimed invention because the recited activity in the claims does not represent a clearly defined function of the molecules of the present

invention, as noted above, and thus fail to limit the scope of the claims. The sequence percentage identity does not represent an effective structural limitation because it says nothing about the conserved regions that are critical to the structure and function of the genus claimed or the sites at which variability may be tolerated and there is no information regarding the relation of structure to function.

Therefore, only isolated nucleic acids of SEQ ID NOS: 2 and 3, and the isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 1, but not the full breadth of the claim, meet the written description provision of 35 U.S.C. §112, first paragraph.

VI. Claim Rejections Under 35 U. S. C. § 102 (e)

(i) The rejection of claims 1, 3, 7, 8, 19, and 20 under 35 U.S.C. 102(e) as being anticipated by Raumann et al. (WO 02/02633 A2, January 10, 2002; prior application US 60/215,391; priority date, June 29, 2000), remains.

Applicants argue that the 102(e) date of the reference, WO 02/02633, is June 27, 2001, i.e., the filing date of WO 02/02633, not June 29, 2000, i.e., the filing date of Priority application US 60/215, 391.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the international filing date of WO 02/02633 is after 11/29/2000, designated the United States, and was published in English by WIPO, **the 102(e) date is the international filing date, or any earlier effective U. S. filing date.** Since the US 60/215,391 has the support for the subject matter, WO 02/02633 is entitled to the 102 (e) date of June 29, 2000, which is earlier than the priority date for the present application.

(ii) The rejection of claims 1, 3, 7, 8, 19, and 20 under 35 U.S.C. 102(e) as being anticipated by Vernet et al. (WO 01/81578 A2, November 1, 2001; prior application US 60/201,474; prior date, May 3, 2000) remains for the same reasons as set forth above.

VII. Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
September 1, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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